

**Independent Oversight
Focus Area Review of**



Safety Component Procurement at DOE Nuclear Facilities

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Office of Independent Oversight
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Table of Contents

	Abbreviations	i
	Executive Summary	iii
1	Introduction	1
2	Positive Attributes	4
3	Weaknesses	6
4	Overall Assessment	8
5	Opportunities for Improvement	10

Abbreviations Used in This Report

CFR	<i>Code of Federal Regulations</i>
CSE	<i>Cognizant System Engineer</i>
DOE	<i>U.S. Department of Energy</i>
EM	<i>DOE Office of Environmental Management</i>
MEL	<i>Master Equipment List</i>
MIP	<i>Maintenance Implementation Plan</i>
NE	<i>DOE Office of Nuclear Energy</i>
NNSA	<i>National Nuclear Security Administration</i>
SC	<i>DOE Office of Science</i>
SC/I	<i>Suspect/Counterfeit Item</i>
SSC	<i>Structures, Systems, and Components</i>
SSO	<i>Safety System Oversight</i>

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Executive Summary

Effective procurement programs are essential elements of nuclear safety programs at U. S. Department of Energy (DOE) nuclear facilities. Procurement processes must ensure that equipment, parts, materials, and related services used in DOE nuclear facility safety structures, systems, and components (SSCs) meet applicable requirements to ensure that the SSCs properly perform their intended safety functions and provide for effective protection of the health and safety of the public, workers, and the environment.

The Office of Independent Oversight, within the DOE Office of Health, Safety and Security, evaluated the effectiveness of implementation of nuclear safety component procurement processes during 14 inspections of DOE nuclear facilities (located at 11 different DOE sites) since 2005. Thirteen of the inspections were performed at sites with operating nuclear facilities, and one was performed at a site with a nuclear facility in the construction phase. This focus area review report analyzes and summarizes the results of those inspections as part of the ongoing effort within the Office of Health, Safety and Security to provide information that will help DOE and contractor management improve their implementation of applicable nuclear safety requirements.

Independent Oversight inspections indicate that most aspects of safety component procurement requirements were effectively implemented at most sites. Over half of the inspected facilities demonstrated effective performance in all of the procurement-related elements that were inspected, and most of the other inspected facilities demonstrated effective performance in most of the procurement elements. The procurement program elements that were effectively implemented at most inspected DOE sites included processes for evaluation and qualification of vendors, receipt of safety items, tracking and traceability of safety parts and materials, and identification and control of suspect/counterfeit parts. Further, almost all sites have well-documented procurement programs and well-trained and experienced personnel, and site performance has been improving as a result of increased management attention and focused efforts to take appropriate action to address identified weaknesses.

However, a number of procurement program elements need additional attention and improvement, as indicated by deficiencies identified at some DOE sites. The procurement element of most concern was the identification, classification, and specification of safety items that fall under the requirements of 10 CFR 830, Subpart A, *Quality Assurance Criteria*, and DOE Order 433.1A, *Maintenance Management Program for DOE Nuclear Facilities*. At several nuclear facilities, deficiencies were identified in master equipment lists, implementation of procurement specification processes, commercial grade dedication and equivalency evaluation processes, and storage of safety components.

In the area of feedback and improvement as applied to procurement elements, DOE sites have made some progress. Most of the sites where Independent Oversight reviewed the assessment programs had performed a number of effective assessments that identified substantive issues and resulted in program improvements. However, the contractor cognizant system engineer and DOE safety system oversight programs were not always sufficiently mature or effective to provide the continual review and evaluation of nuclear safety SSCs, including the associated procurement program elements, required by DOE directives.

Overall, most aspects of procurement programs were effectively implemented at most inspected DOE sites. However, the weaknesses evident in several key areas at some DOE nuclear facilities indicate the need for continued and increased management attention to ensure that the requirements of 10 CFR 830 and DOE Order 433.1A are fully and effectively implemented. The opportunities for improvement listed in Table ES-1 are based on Independent Oversight's collective review of the results of inspections of safety component procurement processes since 2005. These opportunities for improvement and the associated program weaknesses identified in this report should be evaluated by DOE line management and contractor management for applicability at their DOE nuclear facilities, and, where appropriate, corrective actions should be developed and implemented in a timely manner, commensurate with the importance of safety procurement processes to the safety of DOE nuclear facilities.

Table ES-1. Opportunities for Improvement

DOE Line Management (Program Offices and Site Offices)
<ul style="list-style-type: none"> • Ensure adequate oversight of institutional and facility-specific safety component procurement processes. <ul style="list-style-type: none"> ○ Evaluate and adjust the application of resources for assessments of processes for procurement of safety items and services commensurate with their importance to safety and mission objectives. ○ Ensure that the scope of safety system oversight surveillances and assessments appropriately includes the procurement of safety items and services. ○ Monitor the flowdown of institutional-level procurement requirements and their implementation at the facility level, with a particular focus on the weaknesses and opportunities for improvement identified in this report. ○ Adapt the Office of Health, Safety and Security's inspection criteria for site-specific use as a tool to assist personnel who inspect or assess safety procurement programs.
DOE Contractors
<ul style="list-style-type: none"> • Implement measures to comprehensively identify all safety SSCs and services in the facility that are subject to the special procurement requirements of 10 CFR 830, Subpart A, <i>Quality Assurance Criteria</i>, and DOE Order 433.1A, <i>Maintenance Management Program for DOE Nuclear Facilities</i>. • For those items and services subject to the special procurement requirements, ensure that the safety and quality classification of all items, materials, and services to be procured are reflected in appropriate procurement-related documentation. • Establish formal vendor evaluation programs to ensure that vendors have the appropriate facilities, equipment, qualified personnel, procedures, practices, policies, and quality assurance programs to qualify them to supply safety items and services that meet the quality requirements of 10 CFR 830, Subpart A, <i>Quality Assurance Criteria</i>. • Ensure that suitable acceptance plans are developed for each procurement of safety items and services. • Establish formal commercial grade dedication and equivalency evaluation procedures for procurement of safety items or services. • Enhance warehousing and storage of safety items. • Ensure that the cognizant system engineer responsibilities relative to procurement of safety components and services are well-defined and formalized.

1 Introduction

This report summarizes the results of the Office of Independent Oversight's reviews of nuclear safety component procurement at U.S. Department of Energy (DOE) nuclear facilities. This focus area review evaluated the effectiveness of implementation of DOE procurement programs at selected DOE nuclear facilities with respect to the applicable requirements.

The Office of Independent Oversight, within the DOE Office of Health, Safety and Security, is responsible for performing the Department's independent oversight function, including inspections of environment, safety, and health programs at DOE sites. Based on a review of past inspection results, special reviews (e.g., a 2003 Independent Oversight special study of suspect/counterfeit parts), and experience gained through oversight activities, Independent Oversight determined that procurement processes had historically shown a number of persistent weaknesses that were evident at many DOE sites. Therefore, Independent Oversight designated safety component procurement as a focus area for special attention for inspections in recent years.

Scope

This Independent Oversight focus area review evaluated the effectiveness of DOE sites in implementing applicable DOE procurement program requirements. The evaluation is based on data collected since 2005 (a period of more than four years) during scheduled inspections performed by Independent Oversight's Office of Environment, Safety and Health Evaluations at the DOE sites and facilities listed in Table 1. The table also identifies the dates of the inspections and the DOE program office with primary responsibility for each site – the National Nuclear Security Administration (NNSA), the Office of Environmental Management (EM), the Office of Nuclear Energy (NE), and/or the Office of Science (SC). As shown in Table 1 (see page 2), the review encompasses 14 inspections of nuclear facilities at 11 different sites. Thirteen of the inspections were performed at sites with operating nuclear facilities, and one – the inspection of the Hanford Site Waste Treatment Plant – involved a nuclear facility in the construction phase.

During the site inspections, Independent Oversight evaluated the effectiveness of DOE site procurement programs in implementing the applicable requirements for selected systems and components at DOE nuclear facilities. Inspection activities included: reviewing the procurement-related procedures of the various responsible organizations; interviewing personnel responsible for the various facets of procurement; observing actual procurement-related work being performed; reviewing samples of procurement-related documentation from pertinent organizations; inspecting procurement-related facilities, such as receipt areas and warehouses; and inspecting actual products – items or service-related products (e.g. reports, procedures) – that were obtained through the procurement processes.

Table 1. Inspected Sites

Site and Facility	Date	Program Office
Pantex Plant	2/05	NNSA
Y-12 Plant, Building 9212	9/05	NNSA
Savannah River Site, H-Canyon	2/06	EM and NNSA
Oak Ridge National Laboratory, Molten Salt Reactor Experiment	6/06	EM
Hanford Site, T-Plant	10/06	EM
Lawrence Livermore National Laboratory, B-332	2/07	NNSA
Nevada Test Site, Device Assembly Facility	4/07	NNSA
Idaho National Laboratory, Materials and Fuel Complex	7/07	NE
Los Alamos National Laboratory, Weapons Engineering Tritium Facility	12/07	NNSA
Sandia National Laboratories, Annular Core Research Reactor	3/08	NNSA
Y-12 Plant, Building 9204-2E	5/08	NNSA
Oak Ridge National Laboratory, Radiochemical Engineering Development Center	9/08	SC
Hanford Site, Waste Treatment Plant	11/08	EM
Pantex Plant	4/09	NNSA

Procurement Programs and Applicable Requirements

Effective procurement programs are essential elements of nuclear safety programs at DOE nuclear facilities. Procurement processes must ensure that equipment, parts, materials, and related services used in DOE nuclear facility safety structures, systems, and components (SSCs) meet applicable requirements to ensure that the SSCs properly perform their intended safety functions and provide for effective protection of the health and safety of the public, workers, and the environment. An effective procurement process can also prevent adverse economic and programmatic impacts. For example, significant delays and costs could be incurred if a defective component is installed and is later discovered to be defective, requiring a potentially expensive and time consuming removal of installed equipment/materials and extensive actions to determine the extent of the condition.

A comprehensive procurement program has many elements, which are applied during various phases of the lifecycle of safety components and need to be governed by well-defined processes and procedures. These elements include: (1) establishing a well-documented procurement program; (2) identifying safety components and defining technical requirements; (3) identifying qualified vendors; (4) qualifying items or services from non-approved sources or performing equivalency evaluations; (5) performing source and receipt inspections to verify quality; (6) storing the items in a manner that preserves their integrity; (7) tracking and tracing the items through their lifecycle; (8) preventing use of suspect/counterfeit items (S/CIs); (9) applying system engineer oversight to ensure safety system operability and reliability; and (10) performing assessments to ensure that the procurement program is functioning as intended.

These interrelated procurement process elements are typically the responsibilities of many different parts of a facility or site organization, which must effectively coordinate their efforts to ensure that technical

requirements are met. Many of the procurement program elements fall under the responsibility of engineering organizations and the cognizant system engineers (CSEs); DOE Order 420.1B, *Facility Safety*, establishes specific responsibilities and functions for CSEs to ensure that SSCs are properly configured, reliable, and operable. Other site organizations, such as procurement, maintenance, shipping, and quality assurance, also have important roles in the procurement program. Further, a DOE safety system oversight (SSO) engineer also monitors and evaluates the performance of assigned safety systems and of the contractor's activities relative to those systems, as required by DOE Manual 426.1-1A, *Federal Technical Capability Manual*.

The requirements for procurement programs at DOE nuclear facilities originate and flow down from the quality criteria specified in 10 CFR 830, Subpart A, *Quality Assurance Criteria*, § 830.122, and DOE Order 414.1C, *Quality Assurance*. DOE Order 433.1A, *Maintenance Management Program for DOE Nuclear Facilities*, provides additional details for implementing the 10 CFR 830 criteria and requires that contractors establish a maintenance implementation plan (MIP). The MIP must address procurement of parts, materials, and services; a master equipment list (MEL) of all SSCs included in the program; roles and responsibilities for applicable requirements; comprehensive self-assessments of maintenance program activities; and other procurement-related elements.

The Office of Health, Safety and Security has developed inspection criteria for safety component procurement. These criteria are derived from the applicable requirements and are intended to serve as a tool to assist personnel performing inspections or assessments of safety procurement programs. The inspection criteria can be found at: <http://www.hss.energy.gov/IndepOversight/ESHE/docs.html>.

Organization of the Report

Sections 2 and 3 identify positive attributes and weaknesses, respectively. Section 4 provides Independent Oversight's overall assessment of the effectiveness of safety component procurement processes at DOE sites. Section 5 identifies opportunities for DOE line management and contractors to improve procurement programs and processes.

2 Positive Attributes

The following paragraphs describe procurement program elements that were found to be effectively implemented at most of the DOE sites where the element was reviewed.

At most sites, procurement procedures clearly defined the programs necessary for the procurement of safety SSCs and services, and they were generally adequate to address critical program requirements. These procedures typically defined roles and responsibilities, quality requirements in procurement requests, and requirements for identifying and utilizing qualified vendors and documenting quality assurance inspection criteria for receipt inspections. Personnel assigned to the procurement functions were generally well qualified and dedicated to their assigned functions.

Vendor evaluation and qualification processes and performance were generally effective at most sites. With some exceptions, DOE sites had adequate programs to: (1) initially evaluate and qualify vendors and providers, and to maintain their qualifications; (2) perform initial and periodic inspections of vendor facilities; (3) conduct in-plant inspections and testing of procured items; and (4) generate, maintain, and use approved/qualified vendor lists.

Most sites had established effective receipt processes and procedures for items and materials, and had instituted training in those processes. The site procedures typically were effective in addressing critical receipt activities, such as inspection and testing of items, verification of vendors' certificates of compliance, and use of hold tags for discrepant items. Independent Oversight identified a number of instances where site receipt inspections adequately specified verifiable acceptance criteria and methods in inspection plans, and the receipt inspections were performed by well trained and experienced warehouse receipt inspectors.

Tracking and traceability of safety parts and materials were generally effective at most sites. Sites had established adequate processes for traceability of parts and materials, including unbroken, traceable chains of custody for safety parts and material from the vendor's procurement, manufacturing, packaging, labeling, documenting, and delivery processes through the sites' receipt, storage, and issuance processes, and finally, to the end users at the sites. Sites had also established procurement tracking process that were adequate to allow site personnel to ascertain the status of any individual procurement at any stage in the process, as well as adequate processes for storing and retrieving procurement-related documents.

S/CI programs were effectively designed and implemented at all of the inspected sites. Good practices were identified at the inspected sites in a number of areas including: lists of parts and suppliers with histories of S/CIs, defective items, or items that represented safety hazards; receipt inspection reviews against controlled parts lists; inspections of already-installed equipment for S/CIs; maintenance work packages with forms for S/CI inspection of replacement parts; S/CI training; requirements for management notification by anyone

finding potential S/CIs in the workplace; engineering evaluation of potential S/CIs; segregation, tagging, and control of potential S/CIs; documenting and reporting S/CIs; designation of management points of contact for the program; development and maintaining S/CI web pages; and annual program effectiveness assessments by quality assurance. In a number of cases, site processes had successfully identified S/CIs during receipt inspections and thus successfully prevented potentially defective items from being used at the site. For example, one site identified suspect bolts in the base of a check valve that had been procured for the safety fire suppression system and took appropriate actions to replace the bolts and to prevent recurrence (i.e., the valve supplier was removed from the qualified supplier list).

Assessments of safety procurement processes were effectively performed at most sites. Independent Oversight reviewed DOE oversight processes and contractor self-assessments of the procurement processes at selected sites and determined that most had performed adequate assessments that identified substantive issues and resulted in corrective actions. For example, at one site, DOE and contractor assessments identified several instances of incorrectly specified and procured parts; as a result, the contractor undertook a major initiative to understand the causes of the problems and the extent of their condition and to establish corrective actions.

3

Weaknesses

The following paragraphs describe aspects of the procurement program where performance weaknesses were identified at multiple sites. Although the weaknesses noted below were not evident at every site that was evaluated and may not apply to the DOE facilities/sites that were not specifically evaluated, the weaknesses were noted with sufficient frequency to represent generic concerns across the DOE complex. Therefore, they warrant consideration and attention by all DOE sites that procure nuclear safety components.

Some sites did not completely and consistently identify the SSCs that are subject to the safety procurement requirements. Several sites had performance weaknesses that limited the assurance that procured components would perform their safety functions. These weaknesses were noted in four areas. First, some sites did not formally identify and designate precisely which SSCs or activities were covered by the safety component procurement programs. Second, the MELs at some sites did not always identify all of the important data associated with each of the SSCs. Third, procurement specifications for individual procurements did not always identify the safety and quality classification of the items, or did not describe all of the special quality and other requirements for use of all involved parties, including the vendors or providers. Fourth, bills of materials for modifications and/or maintenance activities did not identify the safety classification of items that must be used to ensure that the appropriate special requirements and considerations were applied.

Some sites did not have adequate processes for dedication of commercial grade items and equivalency evaluations of replacement items. Commercial grade dedication is the procurement process for formally evaluating commercial off-the-shelf and custom fabricated items or services (which were not produced under an approved 10 CFR 830 quality assurance program) to determine whether they can be used in safety applications. Equivalency evaluation is the procurement process for formally evaluating potential replacement/substitute items or services to determine whether they can be used in safety applications without adversely impacting safety. These processes were not always implemented with sufficient rigor to ensure that the performance, reliability, quality control, and other attributes of an item or service were adequate to meet the special requirements for nuclear and other special applications in DOE nuclear facilities. For example, at one site, only two of six equivalency evaluation worksheets included credible reconciliations of differences between the original and proposed substitute items, and none adequately compared the failure modes and effects analyses for the original and the replacement part. There were several examples of deficient procurement documentation or receipt inspection, or inadequate evaluation of replacement equipment, so that the installation of a procured item was not demonstrably consistent with applicable design documentation, contrary to the requirements of DOE Order 414.1C, *Quality Assurance*. For example:

- An overpressure protection rupture disk purchased for a safety system was not an exact or equivalent replacement. The MEL and system drawings indicated that the required disk had a nominal

45-pounds-per-square-inch-difference rating and also specified its manufacturer. The “Exact Replacement Determination” form in the work package indicated that the installed replacement had a 40-pounds-per-square-inch-difference rating and was produced by a different manufacturer. The site did not reconcile the differences.

- A single stage safety-related pressure regulator was replaced with a double stage regulator in a purge and exhaust subsystem without adequate analysis and documentation for this change. The analysis did not address and document critical characteristics, such as gas compatibility, required fittings, and needed support. In addition, the original specifications were not compared to the replacement regulator, and the respective failure modes were not compared, as required by the site’s evaluation procedure. Further, an outdated equivalency evaluation form was used, and the pressure range of the replacement was different from the original design, with no reconciliation of the differences.
- For a valve replacement at one site, Independent Oversight identified several deficiencies. The configuration control equipment data sheet required a “bubble tight test,” but the certificate of compliance did not indicate the need for such a test and the receipt inspection did not identify the discrepancy. Documentation was missing critical dimensions, compliance statements, and signatures. The fluid service conditions were not adequately specified. In addition, complete test requirements were not conveyed to the vendor.

Safety-related items were not always adequately stored and controlled in warehouses and other areas where items are stored (e.g., construction site storage areas). At some sites, items were not properly stored in a manner that ensured their integrity and minimized the potential for errors. In some cases, the quality and control of storage environmental conditions were insufficient, items within storage areas were not sufficiently identified or not readily retrievable, safety items were not properly segregated from non-safety items, non-conforming items were not separated from normal stock, and controls to ensure only authorized issuance and use were not always sufficiently defined and implemented. For example, in one instance, a site was storing non-certified pipe in the same pipe racks as certified pipe, thus increasing the potential for using a non-certified pipe where a certified pipe is required. At a nuclear facility construction site, temporary structural steel bolts were not marked to prevent co-mingling with permanent bolts, and some safety bolts, nuts, and washers were stored in conditions that did not meet requirements for protection against environmental factors (e.g., bolts with visible rust were available for use); proper bolt storage is important because bolts that are dirty, rusty, or otherwise altered may not provide proper tension when tightened. At another site, there were no procedures or defined task to perform periodic maintenance on several spare safety fan motors while in storage.

CSE and SSO programs were not always fully effective in evaluating procurement programs and ensuring their effectiveness. Several sites had not implemented an adequate CSE program, as required by DOE Order 420.1B, at the time of their respective inspections. In addition, several DOE sites offices had not implemented an adequate SSO program at the time they were reviewed by Independent Oversight. Several CSE and SSO programs did not include sufficient training in safety procurement and quality assurance processes. Most of the sites that had weaknesses in CSE and/or SSO programs also had weaknesses in safety procurement processes in such areas as the accuracy and level of detail of the MEL, safety classification and technical specifications for replacement components, equivalency determinations, and receipt inspections. Such deficiencies were partially attributable to insufficient CSE involvement and SSO oversight.

4

Overall Assessment

Based on the Independent Oversight inspections of 14 nuclear facilities since 2005, most aspects of safety component procurement requirements were effectively implemented. Over half of the inspected facilities demonstrated effective performance in all of the procurement-related elements that were inspected; these facilities had only a few isolated weaknesses. Most of the other inspected facilities demonstrated effective performance in most of the procurement elements but had weaknesses in a few procurements elements. At two facilities, performance deficiencies were evident in multiple procurement elements.

For the most part, Independent Oversight inspections indicated that the procurement programs have been improving as a result of increased management attention and focus on full compliance with 10 CFR 830 requirements. For example, several sites had ongoing improvement initiatives in place at the time of their inspections to address weaknesses previously identified by internal or external assessments. Further, Independent Oversight's review of corrective action plans indicates that, in most cases, sites are taking appropriate actions to address weaknesses identified by Independent Oversight inspections.

A number of procurement program elements were effectively implemented at almost all inspected DOE sites. Within these elements, sites have generally developed effective processes for ensuring that parts and services meet quality requirements. Procurement elements that were determined to be program strengths included:

- Well-documented procurement programs with well defined roles and responsibilities and dedicated procurement personnel who are experienced and well trained.
- Effective processes for vendor evaluation and qualification, including maintaining and using approved/qualified vendor lists.
- Effective processes for receipt of safety items, including provisions for specification of certificates of compliance for safety items and their verification upon receipt, use of hold tags for non-compliant items, and personnel training.
- Tracking and traceability processes that are effective in ascertaining the physical history, status, and configuration of parts and materials, and accessing the progress of individual procurements through the process. Effective processes for storage and retrieval of procurement records contributed to effective performance in this element.
- Comprehensive and rigorous programs for identification and control of S/CI.

However, a number of procurement program elements need additional attention and improvement, as indicated by deficiencies identified at some DOE sites. The procurement element of most concern was the identification,

classification, and specification of safety items that fall under the requirements of 10 CFR 830, Subpart A, *Quality Assurance Criteria*, and DOE Order 433.1A, *Maintenance Management Program for DOE Nuclear Facilities*. A number of deficiencies were identified at several nuclear facilities in the quality, completeness, and use of MELs. In addition, procurement specifications and bills of materials processes were not always effectively implemented. Improvement is also warranted in procurement elements related to commercial grade dedication and equivalency evaluation processes, and storage of safety components.

In addition, some specific areas within otherwise effective program elements warrant additional attention at DOE sites. Although the higher-tier processes are well documented, the lower-tier implementing procedures at several sites had some shortcomings and were not always linked to the MIPs, as required by DOE Order 433.1A, *Maintenance Management Program for DOE Nuclear Facilities*. Receipt inspections were effective in most cases, but Independent Oversight identified a few instances of deficiencies in inspection plans and criteria (e.g., insufficient specificity in acceptance criteria).

In the area of feedback and improvement as applied to procurement elements, DOE sites have made some progress. For the sites where Independent Oversight reviewed the assessment programs, most had performed a number of effective assessments that identified substantive issues and resulted in program improvements. However, the CSE and SSO programs were not always sufficiently mature or effective to provide the continual review and evaluation of nuclear safety SSCs, including the associated procurement program elements, required by DOE directives. The sites that had weaknesses in CSE and SSO programs typically also had more weaknesses in the procurement elements, confirming the need to ensure that the CSE and SSO programs are effectively designed and implemented.

Overall, most aspects of procurement programs were effectively implemented at most of the inspected DOE sites. However, weaknesses were evident in several key areas at some DOE nuclear facilities indicating the need for continued and increased management attention to ensure that the requirements of 10 CFR 830 and DOE Order 433.1A are fully and effectively implemented.

5

Opportunities for Improvement

Site-specific opportunities for improvement were provided to the responsible DOE and contractor organizations as part of Independent Oversight's report at the completion of each inspection. The following opportunities for improvement are based on Independent Oversight's collective review of the results of all inspections of safety component procurement processes since 2005. DOE line management (program and site offices) and contractor management should evaluate these for applicability and take actions, as appropriate.

DOE Line Management

1. Ensure adequate oversight of institutional and facility-specific safety component procurement processes. Specific actions to consider include:

- Evaluate and adjust the application of resources for assessments of processes for procurement of safety items and services commensurate with their importance to safety and mission objectives.
- Ensure that the scope of SSO surveillances and assessments appropriately includes the procurement of safety items and services.
- Monitor the flowdown of institutional-level procurement requirements and their implementation at the facility level, with a particular focus on the weaknesses and opportunities for improvement identified in this report.
- Adapt the Office of Health, Safety and Security's inspection criteria for site-specific use as a tool to assist personnel who inspect or assess safety procurement programs.

DOE Contractors

1. Implement measures to comprehensively identify all safety SSCs and services in the facility that are subject to the special procurement requirements of 10 CFR 830, Subpart A, *Quality Assurance Criteria*, and DOE Order 433.1A, *Maintenance Management Program for DOE Nuclear Facilities*. Specific actions to consider include:

- Ensure that such measures include processes for classifying all SSCs in formal documentation, such as controlled design drawings and MELs.
- Ensure that all safety and supporting SSCs identified in the safety bases are addressed, as well as any other SSCs that are critical to mission objectives or facility operations or that are appropriate to include for other reasons.

2. **For those items and services subject to the special procurement requirements, ensure that the safety and quality classification of all items, materials, and services to be procured are reflected in appropriate procurement-related documentation.** Specific actions to consider include:
 - Develop facility procedures or revise existing procedures and associated forms to include appropriate requirements for reflecting the safety and quality classification of all items, materials, and services to be procured in appropriate procurement-related documentation, such as specifications and bills of materials.
 - Ensure that site requirements and procedures have provisions for applying quality control requirements and measures appropriate to such classifications to all technical activities related to such procurements.
3. **Establish formal vendor evaluation programs to ensure that vendors have the appropriate facilities, equipment, qualified personnel, procedures, practices, policies, and quality assurance programs to qualify them to supply safety items and services that meet the quality requirements of 10 CFR 830, Subpart A, *Quality Assurance Criteria*.** Ensure that such programs address the following at a minimum:
 - Establishment of formal general criteria, as well as specific criteria unique to each procurement, that vendors must meet in order to be approved.
 - Establishment and maintenance of approved/qualified vendor lists.
 - Establishment of policies and procedures requiring onsite inspections of vendor facilities, initially and periodically, as part of the processes for qualification and maintenance of qualification status.
4. **Ensure that suitable acceptance plans are developed for each procurement of safety items and services.** Specific actions to consider include:
 - Establish procedures requiring development and implementation of acceptance plans.
 - Ensure that procurement-specific acceptance plans include appropriate provisions for verifying that appropriate critical characteristics are met through an efficient combination of required supplier site inspections and test witnessing at appropriate junctures in the manufacturing process, receipt inspections, and post-installation testing.
 - Ensure that the methods used to verify critical characteristics reflect the complexity and importance of the items or services being procured.
5. **Establish formal commercial grade dedication and equivalency evaluation procedures for procurement of safety items or services.** Specific actions to consider include:
 - Establish formal procurement procedures for commercial grade dedication (procurement of safety items or services from vendors without a 10 CFR 830, Subpart A, approved quality assurance program, regardless of whether the item is commercially available, off-the-shelf or custom fabricated).
 - Establish formal procurement procedures for equivalency evaluation (procurement of safety items or services from vendors with a 10 CFR 830, Subpart A, approved quality assurance program, where the item or service is not the same as originally specified, regardless of whether the item is intended as a replacement or planned modification).

- Ensure that such processes use a graded approach based on the complexity of the item or service to provide reasonable assurance that the procured items or services meet the appropriate safety requirements specified for their intended safety application, including requirements relating to form, fit, function, interface, failure mode, reliability, documentation, and quality control.

6. Enhance warehousing and storage of safety items. Specific actions to consider include:

- Establish formal procedural controls for warehousing and storage of safety items.
- Upgrade warehousing facilities and practices to conform to these procedures as needed.
- Ensure that such controls include: the control of storage environmental conditions; clear identification of items with their storage areas for retrievability; segregation of safety from non-safety items and non-conforming items from normal stock; controls to ensure only authorized issuance and use; periodic upkeep activities, such as motor heater energization, lubrication, and motor shaft rotation; and shelf life tracking.

7. Ensure that the CSE responsibilities relative to procurement of safety components and services are well-defined and formalized. Specific actions to consider include:

- Review the facility procurement processes and procedures to identify areas where CSEs could contribute to strengthening configuration management and maintenance of the safety basis of safety SSCs under their purview.
- As needed, modify CSE responsibilities to address such areas.
- Consider including the following aspects of procurement processes in CSE responsibilities:
 - Formalize, as necessary, expectations for CSEs to develop and maintain MEL data relative to their safety SSCs, including review of data in the facility master equipment computerized database for correctness, accuracy, and completeness.
 - Revise CSE training and self-assessment plans, as appropriate, to include quality assurance in procurement processes and specific procedures, such as those for commercial grade dedication and equivalency determination.
 - Ensure that procurement-specific acceptance plans specifying verifiable critical characteristics of safety components, as well as the documentation of receipt inspections and post-installation testing, include provisions for formal CSE review and concurrence.
- Provide CSEs and other personnel who inspect or assess safety procurement programs with suitable tools, such as the Office of Health, Safety and Security's inspection criteria or similar site-specific adaptations of the those inspection criteria.

